



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,615	10/15/2001	Jennifer K. Grenier	031403-9012	2586

23510 7590 07/31/2003

MICHAEL BEST & FRIEDRICH, LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON, WI 53701

EXAMINER

WHISENANT, ETHAN C

ART UNIT PAPER NUMBER

1634

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,615

Applicant(s)

GRENIER ET AL.

Examiner

Ethan Whisenant, Ph.D.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2002 and 04 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 10-12, 14, 20-23, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 4-7, 9, 13, 15-18 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1634

DETAILED ACTION

- 1.** The applicant's Preliminary Amendments filed 08 JAN 02 and 04 FEB 02 have been entered. Following the entry of the Preliminary Amendments, **Claim(s) 1-26** is/are pending.

SEQUENCE Rules

- 2.** This application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Raw Sequence Listing Error Report. See also the Notice To Comply With Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

CLAIM OBJECTIONS

- 3.** **Claim(s) 24** is /are is objected to for the following minor informality.

Claim 24 should end with a period.

35 USC § 112- 2ND PARAGRAPH

- 4.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

5. Claim(s) 20-23, 26 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is indefinite because the phrase "the analyte-specific sequence" on line 2 lacks proper antecedent basis.

Claim 21 is indefinite because it is unclear what is intended by the phrase "detecting the hybridization of at least to extension product to at least two capture oligos." on line 21. It appears that the first "to" in line 21 should actually be "two". This is how this claim has been interpreted as regards its evaluation against the prior art. Please clarify.

Claim 26 is indefinite because it is unclear what is intended by the phrase "non-complementary sequence". Are not all nucleic acid sequences complementary to some other nucleic acid sequence? It appears that the applicant intends the second primer to comprise a first and a second sequence wherein the first sequence is non-complementary to the analyte sequence and a second sequence complementary to the analyte sequence. This is how this claim has been interpreted as regards its evaluation against the prior art. Please clarify.

35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

CLAIM REJECTIONS UNDER 35 USC § 102

7. Claim(s) 1-2, 8, 10-12, 14 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Ugozzoli et al. (1992).

Ugozzoli et al. teach a method of assaying target oligos in a sample comprising all of the steps/limitations recited in Claims 1-2, 8, 10-12, 14. Please note that the limitation wherein the capture oligo is to comprise a molecular recognition sequence comprising at least one non-standard base is met by Ugozzoli et al. wherein these authors teach that their capture oligos are prepared by placing a spacer of three 1,3 propanediol nucleosides at the 3' end of the capture oligo such that the capture oligos will comprise a 3' amino group. Also note that the limitation in Claim 12 wherein the first primer is to comprise a target oligo tagging sequence and a sequence complementary to a first sequence of the analyte, is met by the TYR 1 primer of Ugozzoli et al. For example the five 3' most nucleotides of TYR 1 primer of Ugozzoli et al. are considered to be the sequence complementary to a first sequence of the analyte while the remaining 15 nucleotides (i.e. those nucleotide 5' of the five 3' most nucleotides of TYR 1 primer) have been considered to be the target oligo tagging sequence.

8. Claim(s) 25 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace [WO9421820 (1994)].

Claim 25 is drawn to a kit for assaying an analyte comprising the components. To begin, the kit is to comprise capture oligos coupled to a support wherein the capture oligos are to comprise a molecular recognition sequence having at least one non-standard base. Next the kit is to comprise first primers which are to comprise a tagging sequence and a sequence complementary to a first sequence of the analyte. Finally, the kit is to comprise second primers which are to comprise a sequence complementary to a second sequence of the analyte.

Wallace teaches a kit for assaying an analyte comprising the three components recited in Claim 25. See for example at least page 16 beginning at about line 7. Please note that the limitation in Claim 25 wherein the capture oligo is to comprise a molecular recognition sequence having at least one non-standard base is met by Wallace wherein this author teaches that their capture oligos are prepared by placing a spacer of three 1,3 propane diol nucleosides at the 3' end of the capture oligo such that the capture oligos will comprise a 3' amino group (i.e. exactly as described by Ugozzoli et al. in 1992).

Art Unit: 1634

35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

11. **Claim(s) 3** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ugozzoli et al. (1992) as applied against Claim 1 above and further in view of Hornes et al. [WO9006042 (1990)].

Claim 3 is drawn to an embodiment wherein the support comprises a solid particle.

Ugozzoli et al. teach all of the limitations of Claim 3 except these authors do not teach an embodiment wherein the support comprises a solid particle. However, as the use of solid particle as the support for capture oligos was well known at the time of the invention as evidenced by Hornes et al., it would have been, absent an unexpected result, *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ugozzoli et al. wherein the solid support comprises a solid particle. Absent an unexpected result, the substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for

Art Unit: 1634

their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

CLAIM OBJECTIONS

12. Claim(s) 4-9, 13, 15-18 is /are objected to because it is dependent upon a rejected independent base claim but would appear to be allowable over the prior art of record.

ALLOWABLE SUBJECT MATTER

13. Claim(s) 4-9, 13, 15-24 and 26 would appear to be allowable over the prior art of record. Although each of the steps/limitations are present in the in one or more of the prior art references of record. No one reference taught a method of assaying a target sequence comprising all of the steps/limitations recited in Claim(s) 4-9, 13, 15-24 and 26. Furthermore the examiner can find no teaching present in the prior art that would have motivated the ordinary artisan to combine the various prior art references of record to arrive at the invention set forth in Claim(s) 4-9, 13, 15-24 and 26.

CONCLUSION

14. Claim(s) 19 is/are allowable while Claim(s) 1-18 and 20-26 is/are rejected and/or objected to for the reason(s) set forth above.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.


The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to

Application/Control Number: 09/977,615

Page 7

Art Unit: 1634

Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



ETHAN WHISENANT
PRIMARY EXAMINER

SUBSTITUTE PTO-948

DRAWINGS

The drawings filed with this application have been approved by the Examiner under 37 CFR 1.84 or 1.152.